

Public declaration regarding the manufacture and use of in-house devices by health institutions

Name of health institution

Department of Clinical Biochemistry

Odense University Hospital

Address

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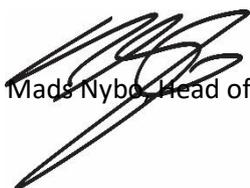
Declaration

Department of Clinical Biochemistry, Odense University Hospital, declares that the devices described in the accompanying table are only manufactured and used at the department and do meet the applicable general safety and performance requirements (GSPR) of the medical devices Regulation (EU2017/745) or of the *in vitro* diagnostic medical devices Regulation (EU 2017/746). All analyses fulfill the quality demands formulated in ISO 15189. A reasoned justification is provided in case applicable general safety and performance requirements are not fully met.

Date and location

Odense, May 15 2024

Name, function and signature of responsible person(s)



Mads Nybo, Head of Department

List of Medical Devices

| Device identification (e.g. name, description, reference number) | Device type (IVD/ MD) | Devi - ce class | Intended purpose | Medical device documentation (application/kits/analyses etc) | Appli cable GSPR met? (Y/N) | Information on and justification for applicable GSPR that are not fully met (using the numbering as in Annex I of the IVDR/MDR) |
|--|--------------------------------|-----------------------|---|--|---|---|
| 2 ICP-MS systems consisting of: ICP-MS, Agilent 7850, SG23261364 and SG23251360. SPS Autosampler, AU231215670 and AU231210668. ISIS fast valve, 23C-0337C og 23C-0323C | IVD | B | Analysis of Cu, Zn, Cr, Co, Se in plasma/serum, Pb in whole blood and Cu in urine | Zn;P (DokID: 1053282) Cu;P (DokID: 1050981) Pb;B (DokID: 323081) Se;P (DokID: 653482) Cr;P (DokID: 958644) Co;P (DokID: 958644) Cu;U (DokID: 784193) | Y | None declared |
| Cobas8000, Roche | IVD | B | Analysis of Albumin, Bilirubin, Citrate, Cholesterol, Creatinine, LDH methotrexate, pancreas amylase, protein, triglyceride, and, urea in body fluids | Albumin (Albumin gen.2, Roche) Bilirubin (Bilirubin total gen.3, Roche) Citrat (Art no E8230, r-biopham) Cholesterol (Kolesterol gen.2, Roche) Creatinine (Kreatinin plus ver.2, Roche) LDH (Laktatdehydrogenase ifølge IFCC ver. 2, Roche) MTX (ARK Methotrexate, ARK Diagnostics) AmylP (Pancreas-α-amylase EPS, Roche) Protein (Totalprotein gen.2, Roche) Trig (Triglycerider, Roche) Urea (Carbamid/BUN, Roche) | Y | None declared |
| Nano-LC-MSMS system consisting of: Dionex Ultimate 3000 nano system | IVD | B | Analysis of protein composition of Congo Red positive tissue biopsies | Relative composition of the amyloid signature proteins ApoE, ApoA4, Serum amyloid P, and amyloidogenic proteins, commonly Ig light chain kappa, Ig light chain lambda, serum amyloid A and transthyretin (PMID: 31752543) | Y | None declared |
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